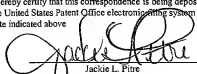


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/542,983
Filed: June 23, 2000
Confirmation No.: 7824
First Named Inventor:
Horst G. Zerbe

Title: ORAL DOSAGE
FORMULATION

Examiner: Ahmed, H.
Group/Art Unit: 1615
Atty. Dkt. No: 6165-10702

CERTIFICATE OF ELECTRONIC TRANSMISSION UNDER 37 C.F.R. §1.8 DATE OF DEPOSIT: 9/25/03 I hereby certify that this correspondence is being deposited with the United States Patent Office electronic filing system on the date indicated above  Jackie L. Pire

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant submits the following Appeal Brief in support of claims 1-15, 17-19, 28 and 30 of the above-referenced application. Appellant submits that each of these claims is patentable and in condition for allowance.

I. Real Party in Interest

The Real Party in Interest for the appealed application is Akela Pharma SRL, a corporation having a place of business at Windmark, Harts Gap, Christ Church, Barbados.

II. Related Appeals and Interferences

There are no related appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-64 have been entered in the case. Claims 16, 20-27, 29, and 31-64 have been cancelled. Claims 1-15, 17-19, 28 and 30 are pending. Claim 1 has been rejected. Claims 2-15, 17-19, 28, and 30 have been withdrawn. No claims have been allowed. Claims 1-15, 17-19, 28, and 30 are being appealed.

IV. Status of Amendments

An Office Action was mailed on December 23, 2008. No amendments have been made to the claims since the mailing of this Office Action.

V. Summary of Claimed Subject Matter

This invention generally relates to oral dosage formulations. See Specification, page 1, lines 4-5 (all future page, paragraph, and line references in this section refer to the Specification unless otherwise indicated). In one embodiment, a multi-layer oral dosage form, includes: (a) a matrix core comprising a therapeutically effective amount of a first drug, wherein the matrix core allows sustained release of the first drug; a first layer, which is in contact with said matrix core, comprising a first portion of a pharmaceutically effective amount of a second drug, wherein the first layer allows sustained release of the second drug; and a second layer, which is also in contact with said matrix core, comprising a second portion of the second drug, wherein the second layer allows immediate release of the second drug. (Specification, page 5, line 24 – page 6, line 7)

VI. Grounds of Rejection to be Reviewed on Appeal

1. Claim 1 is finally rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 4,946,685 to Edgren et al. (hereinafter “Edgren”).

VII. Argument

Claim 1 is finally rejected under 35 U.S.C. §102 as being anticipated by Edgren. Appellants traverse this rejection for the following reasons.

The standard for “anticipation” is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. *Hybritech, Inc. v.*

Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed.Cir. 1986); *In re Donahue*, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed.Cir. 1985).

Claim 1 describes a combination of features including:

- (a) a matrix core comprising a therapeutically effective amount of a first drug, wherein the matrix core allows sustained release of the first drug;
- (b) a first layer, which is in contact with said matrix core, comprising a first portion of a pharmaceutically effective amount of a second drug, wherein the first layer allows sustained release of the second drug; and
- (c) a second layer, which is also in contact with said matrix core, comprising a second portion of the second drug, wherein the second layer allows immediate release of the second drug.

The final Office Action, mailed December 23, 2008, takes the position that an oral dosage form having these characteristics is anticipated by Edgren. Specifically, the Office Action equates lamina 12 and lamina 13 of Edgren with Appellant's claimed matrix core and first layer. The Office Action equates coating 16 of Edgren with Appellant's claimed second layer. Appellant respectfully disagrees.

Applicant's claims include the features that the matrix core allows "sustained" release of the first drug and the first layer allows "sustained release" of the second drug. In order to anticipate Appellant's claims, lamina 12 and lamina 13 would need to both be sustained release layers. Applicant submits that laminate layer 13, however, does not allow "sustained release of the first drug." Instead laminate layer 13 of Edgren appears to be an instant release layer.

Edgren teaches that an oral dosage form as depicted in cross sectional view in FIG. 3. With respect to the oral dosage form, Edgren states:

FIG. 3 illustrates another manufacture provided by the invention. In FIG. 3, a dosage form 10 is seen in opened view and it comprises body 11, first lamina 12, a drug 14 in first lamina 12, second lamina 13 and a drug 14 in second lamina 13. Drug 14 present in first lamina 12 and in second lamina 13 may be the same or different. In FIG. 3, dosage form 10 additionally comprises an external coat 15. Coat 15 surrounds internal lamina 12 and internal lamina 13. ... In FIG. 3, dosage form 10 comprises optional drug 16 in coat 15. The presence of drug 16 provides instant drug release when dosage form 10 is introduced into an aqueous environment of use. The instant drug 16 is supplemental to the instant and prolonged drug delivery of dosage form 10, for improved drug therapy. (Edgren, Col. 6, line 55 – Col. 7, line 37)

As noted above, the oral dosage form of Edgren can include a first lamina 12 and a second lamina 13 surrounded by a coat 15. Coat 15 may provide “instant drug release” when a drug is included in the coat. The Office Action appears to equate the combination of coat 15 and drug 16 with Appellant’s claimed second layer. The main portion of the dosage form appears to be designed by Edgren to provide “instant and prolonged drug delivery.” AS noted in the above-cited passage the release of drug from the coating layer is supplemental to the instant and prolonged release of the dosage form of Edgren. Applicant submits that, contrary to the allegations of the Office Action, Edgren appears to teach an oral dosage form that includes a layer that provided instant release, a layer that provides prolonged release, and a coating that provides instant release of a drug. In contrast, Appellant’s claims are generally directed to an oral dosage form that includes two sustained release portions and a single instant release portion. For at least these reason’s Appellant’s claims are not anticipated by Edgren.

The Office Action contends that “both lamina 12 and lamina 13 can be formulated to be sustained release layers.” Applicant disagrees. Edgren teaches that:

The dosage form of the invention provides an unique method for obtaining the maximum therapeutic benefit of a drug. The method comprises: (1) admitting the dosage form into a biological fluid environment of use, said dosage form comprising: (a) a drug delivery lamina comprising a cellulose ether composition

means and a drug for continuously and slowly delivering the drug at a rate controlled by the lamina over an extended period up to 21 hours; and (b) a drug releasing lamina comprising a cellulosic ether composition means for delivering the drug immediately and over an unextended period up to 3 hours at a rate controlled by the lamina; and (c) delivering the drug from the unextended lamina and the extended lamina to the environment of use to provide the therapeutic effect of the drug.

As noted above, Edgren appears to be directed to a dosage form that provides “instant and prolonged drug delivery” which may be further coated with an instant drug release coating. Thus, Edgren appears to teach a dosage form, of the invention, that includes two instant release layers and a sustained release layer. Forming an oral dosage form that included two sustained release layers appears to go against the teaching and intent of the object of the invention of Edgren.

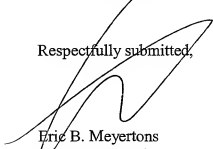
Applicant’s claimed dosage form includes two sustained release layers (matrix core layer and first layer) and an immediate release layer (second layer). For at least these reasons, Applicant submits that Edgren does not appear to teach or suggest these features.

VIII. Conclusion

For the foregoing reasons, it is submitted that the Examiner’s rejection of claim 11 was erroneous, and reversal of his decision is respectfully requested. Appellant also requests rejoinder of claims 2-15, 17-19, 28, and 30 upon allowance of claims 1, which is a generic claims to claims 2-15, 17-19, 28, and 30.

Appellant respectfully requests a one-month extension of time to file the Appeal Brief. A Fee Authorization is attached for the filing of this appeal brief and a one-month extension of time. If any additional extension of time is required, Appellant hereby requests the appropriate extension of time. If any fees are omitted or if any additional fees are required or have been overpaid, please appropriately charge or credit those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/6165-10702/EBM.

Respectfully submitted,



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IX. Claims Appendix

The claims on appeal are as follows:

1. A multi-layer oral dosage form, comprising:
 - (a) a matrix core comprising a therapeutically effective amount of a first drug, wherein the matrix core allows sustained release of the first drug;
 - (b) a first layer, which is in contact with said matrix core, comprising a first portion of a pharmaceutically effective amount of a second drug, wherein the first layer allows sustained release of the second drug; and
 - (c) a second layer, which is also in contact with said matrix core, comprising a second portion of the second drug, wherein the second layer allows immediate release of the second drug.
2. A multi-layer oral dosage form, according to claim 1 further comprising in the first layer an additional amount of the first drug, wherein the first layer allows sustained release of the first and second drugs.
3. The multi-layer oral dosage form as defined in claim 1, wherein said matrix core further comprises insoluble polymers and adjuvants.
4. The multi-layer oral dosage form as defined in claim 3, wherein said polymers are selected from the group consisting of insoluble cellulosic materials, polyvinyl acetates, polyvinyl alcohols, polyethylene oxides, metacrylates, and non-crosslinked polyvinylpyrrolidone.

5. The multi-layer oral dosage form as defined in claim 3, wherein said adjuvants comprise sugars, colloidal silica, calcium diphosphate, talc and magnesium stearate.
6. The multi-layer oral dosage form as defined in claim 3, wherein said first layer further comprises water-soluble and/or gel forming polymeric materials.
7. The multi-layer oral dosage form as defined in claim 3, wherein said second layer further comprises pharmaceutical acceptable excipients selected from the group consisting of cellulose derivatives, cross-linked polymers, sugars, soluble salts, colorants, fillers, disintegrants, anti-lacking agents and anti-static agents.
8. The multi-layer oral dosage form as defined in claim 6, wherein said first layer comprises from about 15 to about 95% of the second drug.
9. The multi-layer oral dosage form as defined in claim 7, wherein said second layer comprises from about 5 to about 85% of the second drug.
10. The multi-layer oral dosage form as defined in claim 1, wherein said first drug is an NSAID.
11. The multi-layer oral dosage form as defined in claim 10, wherein said NSAID consists essentially of diclofenac.
12. The multi-layer oral dosage form as defined in claim 11, comprising from about 50 to about 150 mg of diclofenac.
13. The multi-layer oral dosage form as defined in claim 12, comprising about 75 mg of

diclofenac.

14. The multi-layer oral dosage form as defined in claim 10, wherein said NSAID consists essentially of aspirin.

15. The multi-layer oral dosage form as defined in claim 12, comprising from about 50 to about 150 mg of aspirin.

17. The multi-layer oral dosage form as defined in claim 1, wherein said second drug is an H2-receptor antagonist.

18. The multi-layer oral dosage form as defined in claim 17, wherein said H2-receptor antagonist consists essentially of famotidine.

19. The multi-layer oral dosage form as defined in claim 18, comprising from about 20 to about 60 mg of famotidine.

28. A method for treating and preventing osteoarthritis in patients susceptible to developing NSAID induced gastric and duodenal ulcers comprising administering a multi-layer oral dosage form as defined in claim 1.

30. A method for preparing a multi-layer oral dosage form, comprising:

- (a) preparing a sustained release matrix core comprising a therapeutically effective amount of a first drug or pharmaceutically acceptable salts thereof;
- (b) preparing a sustained release blend comprising a first portion of a pharmaceutically

effective amount of a second drug or pharmaceutically acceptable salts thereof;

(c) preparing an immediate release blend comprising a second portion of the second drug or pharmaceutical acceptable salts thereof; and

(d) combining, by compressing, the matrix core of step (a), the sustained release blend of step (b) and the immediate release blend of step (c) such that the sustained release blend and the immediate release blend are in contact with the matrix core.

X. Evidence Appendix

No evidence submitted under 37 CFR §§ 1.130, 1.131 or 1.132 or otherwise entered by the Examiner is relied upon in this appeal.

XI. Related Proceedings Appendix

There are no related proceedings.